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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/030,985	02/26/1998	LOUIS D. FALO JR	214001-00648	8081

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STEPHEN A BRENT
FOLEY & LARDNER
WASHINGTON HARBOUR
3000 K STREET NW SUITE 500
WASHINGTON, DC 20007-6109

EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/30/2002

39

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/030,985

Applicant(s)
Falo et al.

Examiner
G.R. Ewoldt

Art Unit
1644



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 7, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15, 17-24, 37, and 38 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 13-15, 17-24, 37, and 38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The response, filed 7/12/02, has been entered.

2. Applicant's election of the species "tumor cell," without traverse, in Paper No. 38, filed 10/07/02, is acknowledged.

3. Claims 13-15, 17-24 and 37-38 are currently pending in this application.

4. In view of Applicant's Remarks, all previous rejections have been withdrawn.

5. The following are new grounds for rejection.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 37 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically, a composition of Claim 13 wherein the products of co-culture are irradiated "before administration," has no antecedent basis in Claim 13.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 13-15, 17-24 and 37-38 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the

relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, "a composition".

Applicant's amendment, filed 4/17/00, fails to indicate where support for the change of "a formulation" to "a composition" can be found in the specification. A review of the definitions of both words shows that "composition" is a broader term than is "formulation" in that a formulation consists of a product produced by a specific formula whereas a composition comprises any product of mixing or combining, see *Webster's Ninth New Collegiate Dictionary*, 1990.

10. Claims 17, 18, 22, and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a formulation comprising a DC and a tumor cell in a ratio of 6:1,

does not reasonably provide enablement for:

a formulation comprising a DC and a tumor cell in a ratio of 1:100 and 100:1, or 1:10 and 10:1.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention.

The invention of the instant claims is drawn to a formulation for inducing an immune response consisting of a co-culture of DCs and tumor cells.

Regarding the breadth of the claims, Applicant's post-filing publication (Celluzzi et al., 1998) teaches that a formulation in the ratio of 6 DCs to 1 tumor cell is capable of inducing an immune response. The reference also teaches that neither DCs alone nor tumor cells alone are capable of inducing said response. Accordingly, a formulation that consists of 100 DCs to 1 tumor cell, or 10 tumor cells to 1 DC, would not be expected to

function in the instant formulation for its intended use, as these formulations would more closely resemble DCs alone or tumor cells alone, respectively. Therefore, the claimed compositions must be considered highly unpredictable and requiring of undue experimentation in employment for their intended use.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Thus, in view of the quantity of experimentation necessary, the lack of sufficient working examples encompassing the breadth of the claimed invention, the unpredictability of the art, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 13, 14, and 17-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Thurnher et al. (1996).

Thurnher et al. teaches a composition comprising a co-culture of DCs and tumor cells (see particularly page 3, column 1, last paragraph - column 2, first paragraph and column 2, last paragraph). Note that the reference does not specifically teach the sources of the DCs as set forth in Claim 2, however, the claim encompasses sources that would include the mature DCs of the reference, i.e., lymph node and spleen DCs are mature DC. Additionally, while the reference does not teach specific ratios of DCs to tumor cells, the recitation of "about" in claims 17-19 renders the product of the claims broad enough to encompass the product of the reference.

The reference anticipates the claimed invention.

13. Claims 13, 15, and 17-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Olstad et al. (1980).

Olstad et al. teaches a composition comprising a co-culture of macrophages and sarcoma cells (see particularly Abstract). Additionally, the reference teaches a ratio of 2.5 to 1 (page 2055, column 1, first paragraph) which is within the ranges of

Claims 17 and 18 and which can be considered to be "about" 6:1.

The reference anticipates the claimed invention.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone numbers are 703-872-9306 (before final) and 703-872-9307 (after final).



G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
December 27, 2002